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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,711	07/21/2003	Duane D. Blatter	11502/25:1 US	7568

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EXAMINER	
DEAK, LESLIE R	
ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/624,711	BLATTER ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/26/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 recites the limitation "the non-native materials" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 8, and 10-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 4 of U.S. Patent No. 6,595,941 to Blatter. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application claims a

broader embodiment of the patented invention. Specifically, the patented invention includes the steps of providing occludable extraction and delivery tubes, anastomosing one end of the tubes to a blood vessel, occluding the access tubes, opening the access tubes, sending blood to a treatment device, and reoccluding the access tubes when the treatment is completed.

5. Claims 2, 3, 17, 18, 22, 26-34, and 39-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 20 of U.S. Patent No. US 6,663,590 to Blatter. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite an access tube with a selective occluder with a physiologically active agent disposed on the occluder wherein the occluder is accessed via a self-sealing port. Further, the '590 patent claims a graft vessel means with an anastomosis end and a port end. The "means for" language of the '590 patent allows one to turn to the drawings and specification in order to interpret the claims. As such, the port end, as illustrated by the drawings (see FIG 7A), serves to close the end of the access tube opposite the anastomosis end. Similarly, the graft vessel means is adapted to anastomose a vessel at its anastomosis end without extending significantly into the vessel. The illustrated graft vessel (see, again FIG 7A) has anastomosis components, including an anastomosis ring. Therefore, the instant invention is unpatentable over the '590 patent. The instantly claimed method recites steps of providing and using the previously patented structure, therefore the recitation of said structure in a prior patent renders the steps of supplying said structure obvious.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 9-15, 17, 18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,822,341 to Colone. Colone discloses a vascular access fistula with access tubes 36, 38, and corresponding port holes that may be anastomosed with sutures to the sidewalls of vessels 68 and 70, providing fluid communication. The access tubes are occluded by valve 22 that may be opened and closed by moving the occluding valve to establish and halt flow through the tubes to a blood treatment machine. The occluding valve is in a closed position by default, creating a self-sealing port in fluid communication with the access tube and the occluder. Examiner is using the broadest reasonable interpretation of "fluid occluder" to mean a device that may occlude fluid flow.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 3-7, 21-30, 31, and 33-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,822,341 to Colone in view of US 5,797,879 to DeCampli et al. Colone discloses the apparatus as claimed with the exception of a fluid occluder with a port that is configured to allow fluid transport in order to inflate and deflate the occluder. DaCampli discloses a vascular graft 21 with a selectively adjustable balloon occluder 23 therein. The occluder is connected via lumen 25 to access port 24 that allows for the injection and withdrawal of an inflation medium (see column 5, lines 50-55). The occluder is designed to allow for repeated accurate regulation of blood through the graft without the need for surgical intervention and without damage to the graft (see column 4, lines 10-25). Therefore, it would have been obvious for one of ordinary skill in the art to use inflatable balloon occluders as disclosed by DeCampli in the vascular access device disclosed by Colone in order to provide for selective restriction of blood flow through the graft without infolding or crimping of the graft material, as taught by DeCampli. With regard to applicant's claims drawn to the inflation medium, DeCampli specifically discloses that his occluder may be filled with low-viscosity saline or high-viscosity, often gel-like glycerine (see column 8, lines 5-10).

10. Claims 8 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,822,341 to Colone in view of US 5,797,879 to DeCampli et al, further in view of US 6,200,257 to Winkler. Colone and DeCampli disclose the apparatus and method as claimed with the exception of providing a pharmacologically active agent on the occluder. It is well-known in the art to provide occluding balloons with a permeable membrane and a pharmacologically active substance that may elute from the occluder,

as disclosed by Winkler. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to add a pharmacologically active substance to the occluder, as disclosed by Winkler to the access device and occluder disclosed by Colone and DeCampli in order to selectively administer a pharmacologically active agent to a particular targeted area of the patient, as taught by Winkler.

11. Claims 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,822,341 to Colone in view of US 4,421,507 to Bokros. Colone discloses the method and device as claimed with the exception of placing the access device in a percutaneous position. Bokros discloses a percutaneous access port with a plug or cap that allows patients to self-administer medications and treatments directly to his or her own vascular system without repeatedly puncturing the skin, which may lead to infection and scarring. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to place the access device disclosed by Colone in a percutaneous position with a plug in order to allow patient access with minimal scarring and infection, as taught by Bokros.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. US 5,421,814 Geary et al

i. Dialysis access port with occluder

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lrd
22 September 2005

PATRICIA BIANCO
PRIMARY EXAMINER